OCCUPATIONAL SAFETY AND HEALTH STANDARDS BOARD

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FINAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

TITLE 8: Division 1, Chapter 4, Subchapter 7, Group 16, Article 109, New Section 5199.1 of the General Industry Safety Orders

Aerosol Transmissible Diseases -- Zoonotic

MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE 45-DAY PUBLIC COMMENT PERIOD

There are no modifications to the information contained in the Initial Statement of Reasons (ISOR) except for the following substantive, and/or sufficiently related modifications that are the result of public comments and Board staff evaluation.

This proposed rulemaking action contains nonsubstantive, editorial, reformatting of subsections, and grammatical revisions. These nonsubstantive revisions are not all discussed. However, these proposed revisions are clearly indicated in the regulatory text in underline and strikeout format. In addition to these nonsubstantive revisions, the following actions are proposed:

Subsection (a)(1)(A)8.

As originally noticed this subsection included, within the scope of this section, operations involving the cleanup, decontamination, or disinfection of areas potentially contaminated with zoonotic aerosol transmissible pathogens. A modification is proposed to change this wording to include within the scope "Zoonotic ATP [aerosol transmissible pathogens] incident response operations as defined below." The necessity and purpose of this modification is to clarify, in response to comments, that this scope item pertains to operations that are undertaken to control infection of zoonotic ATPs in animals and to clean up areas that are potentially contaminated by those animals.

Subsection (a)(1)(B)

As originally noticed, this subsection stated that this section did not apply to establishments or portions of establishments in which the only exposure to animal products, byproducts or wastes is to carcasses or portions thereof that have passed an inspection in accordance with the USDA or CDFA. In response to comments, a phrase has been added clarifying that the inspection must have determined that the product is fit for human consumption. The purpose and necessity of this is to ensure that the regulated public understands the use of the term "passed" as used in the standard.

Subsection (a)(2)(A)

As originally published this subsection required employers within the scope of this standard to establish, implement and maintain effective procedures for controlling employee exposure to

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> zoonotic ATPs. In response to comments, changes in wording are proposed to clarify that this subsection applies to all employers covered by this standard, and it requires each employer to address zoonotic ATP hazards through their injury and illness prevention plan (IIPP), in accordance with Section 3203. This includes the investigation of occupational injuries and illnesses, and provision of sanitation and training. The standard also states that "where applicable" these procedures must also include biosecurity and personal protective equipment. A sentence has been added to this subsection to clarify that compliance with this subsection satisfies the employer's responsibility under this subsection unless employees participate in any other operations listed below (in scope subsections (a)(2)(B) through (a)(2)(G)). The purpose and necessity of these changes is to clarify that all employers whose employees have contact with animals as described in the scope section must take certain basic measures to identify, evaluate and control exposures, as are currently required under Section 3203. The purpose and necessity of these changes is also to further clarify that if none of the circumstances exist that would require additional protective measures (as identified in subsection (a)(2)(B) through (a)(2)(G)), compliance with the measures described in this subsection will meet the requirements of this standard.

Subsection (a)(2)(B)2

As originally noticed, this subsection required employers to comply with subsections (b) and (e) if they had certain work operations that involved collecting and disposing of wildlife for which an alert regarding zoonotic infection had been issued by certain government agencies. The wording of this subsection has been modified in response to comments to add a phrase indicating that the alert triggering these requirements is one that is applicable to the employer's operations based on conditions specified in the notice. Two examples of these conditions are provided, which are the geographic area and the species or type or animal. The purpose and necessity of this change is to clarify that the enhanced protections triggered by an alert are only triggered when the alert is relevant to the work operation. The term "zoonotic ATP infection" has replaced the term "zoonotic infection." The purpose and necessity of this change is to clarify that only alerts regarding the presence of infection with zoonotic pathogens transmitted by aerosols will trigger the additional protective measures.

New Subsection (a)(2)(F)

In response to comments, a new subsection (a)(2)(F) has been added to clarify the responsibility of employers with vertebrate animal research facilities that come under this standard. This subsection requires those facilities, often called "vivariums," to perform a risk assessment in accordance with Biosafety in Microbiological and Biomedical Laboratories (which is defined and incorporated by reference in subsection (a)(4)). These facilities are further required to comply with subsection (e), which addresses recordkeeping. Further, when the risk assessment determines that "Animal Biosafety Level 3" practices are required, employers would be required to comply with subsection (d) as well. The purpose and necessity of these changes is to permit these employers to use existing, accepted, risk-assessment methodology and control methods, and to be consistent with proposed Section 5199.

Subsection (a)(3)

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As originally noticed this subsection required that medical surveillance and management be provided at a reasonable time and place for the employee, at no cost to the employee and during working hours. The term "medical surveillance and management" has been changed to "medical services," to reflect that some medical services to be provided under this section are not included within the common use of the term "medical surveillance." The term "medical services" also includes those services included under "medical management," so that term is deleted. The purpose and necessity of this change is for clarity.

Subsection (a)(4) Definition of "Alert"

A modification is proposed to add the word "public" before the phrase "announcement or notification." The purpose and necessity of this change is to clarify, in response to comments, that the announcements that will trigger additional actions under the standard are those that are publicly issued. National and state plans for avian influenza and other potential zoonotic disease outbreaks include the public announcement regarding the detection of a disease in animals. The lead agency for these announcements is the California Department of Public Health; however, announcements may be made by the local health officer, or by several other agencies that are listed in subsection (b). A further change is proposed to indicate that the announcement or notification must be in regards to a "detected" zoonotic "ATP" hazard. The purpose and necessity of these changes are to clarify that the alerts that trigger additional protective measures by this section are those that relate to detection of zoonotic aerosol transmissible pathogens (as compared to fact sheets for the general information of the public that do not relate to a specific detection of a hazard.) An additional change is proposed to reflect that an alert may be issued for a species or type of animal and/or a geographic area, and the terms "establishment" and "type of work" have been deleted. The purpose and necessity of this change is clarity and consistency within the text.

Subsection (a)(4) New Definition, "Animal Biosafety Level 3 (ABSL-3)"

In response to comments, a new definition for "Animal Biosafety Level 3 (ABSL-3) is proposed. This term is used to define the circumstances in which additional protective measures are required to protect employees from aerosol transmission of zoonotic pathogens from infected animals. This term is defined to be consistent with Biosafety in Microbiological and Biomedical Laboratories, which recommends protective measures for vertebrate animal research facilities. The purpose and necessity of this change is to clarify the circumstances under which an animal research facility must adopt additional protective measures and must comply with subsection (d).

Subsection (a)(4) New Definition "Biosafety in Microbiological and Biomedical Laboratories (BMBL)"

In response to comments, a new definition for the term "Biosafety in Microbiological and Biomedical Laboratories" is proposed to define a referenced publication for control of zoonotic hazards to employees in vertebrate animal research facilities. This document is incorporated by reference for this purpose. The purpose and necessity of this definition is to incorporate the risk assessment and control methodology that is nationally recognized by public health authorities.

Subsection (a)(4) Definition of "Biosecurity procedures"

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In response to comments, the definition of "biosecurity procedures" has been expanded to further explain how this term is to be interpreted in the context of this standard. It explains that the purpose of biosecurity procedures is to prevent direct or indirect transmission of zoonotic ATPs from animal to animal, to the environment, and to people who come into areas where animals are housed, or through the debris from those areas. This definition further explains that the type of biosecurity procedures that are necessary depend upon the operation and clarifies that absent certain triggering circumstances, biosecurity beyond basic sanitation measures are not typically necessary for incidental removal of animal carcasses or other waste, such as nests. The purpose and necessity of this change is to clarify what is meant by "biosecurity procedures" in the context of this standard.

Subsection (a)(4) New Definition "Zoonotic ATP incident response"

In response to comments, a definition for the term "zoonotic ATP incident response" is proposed. The purpose and necessity of this definition is to identify those operations that require additional control measures due to the potential of exposure to higher levels of infectious aerosols.

Subsection (a)(4) Definition of "Untreated animal products, byproducts or wastes." In response to comments, the definition of "untreated animal products, byproducts or wastes," has been modified to include the phrase, "and has been determined to be fit for human consumption," in relation to passing an inspection in accordance with the regulations of the USDA or CDFA. The purpose and necessity of this modification is to clarify the meaning of the term "passed an inspection."

Subsection (b)(1)

In response to comments, the term "ATP" has been inserted into the phrase "collecting and disposing of wildlife for which an alert regarding the potential of zoonotic <u>ATP</u> infection has been issued by the CDC." The purpose and necessity of this change is to clarify that only alerts related to the potential of zoonotic ATP infection are addressed by this subsection, and for consistency within this standard.

Subsection (b)(2)(D)

As originally noticed, this subsection used the term "medical surveillance" to refer to preventive medical measures and disease detection. A change is proposed to use the term medical services, to be consistent with the common use of the term surveillance. The purpose and necessity for this change is to provide clarity and consistency within the text.

Subsection (c)(2)(E)

A change is proposed to add the phrase medical "services, including" surveillance, vaccinations and prophylaxis. This change is proposed to be consistent with the common use of the term "surveillance." The purpose and necessity of these changes is to provide clarity and consistency within the text.

Subsection (c)(2)(F)

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A change is proposed to replace the phrase "medical surveillance program including recommended vaccinations or prophylaxis," with the phrase "medical services program including recommended surveillance, evaluations, vaccinations and prophylaxis." The purpose and necessity of this change is to be consistent with the common use of the term surveillance and to make the training requirements addressed by this subsection consistent with the rest of subsection (c).

Subsection (d)(1)(C)8

A change is proposed to change the term medical "surveillance" to medical "services," to be consistent with the common use of the term surveillance. The purpose and necessity of this change is to provide clarity within the text.

Subsection (d)(4)

As originally noticed, this subsection required an employer to provide certain respiratory protection unless the employer had determined through objective evidence that such use was not necessary. A change is proposed to require the employer to demonstrate through objective evidence that respirator use is not required, if the employer determines not to use respirators. A similar change is proposed to require the employer to demonstrate through objective evidence that elastomeric facepiece respirators or powered air purifying respirators are not required for employees who work in enclosed areas. This change is proposed in response to comments. The purpose and necessity of this change is to clarify that it is the employer's responsibility to demonstrate that respirator use, or the specific type of respirator use, is not necessary to protect employees.

Subsection (d)(8)

A change is proposed to change the term medical "surveillance" to medical "services," to be consistent with the common use of the term surveillance. The purpose and necessity for this change is to provide clarity in the text.

Subsection (d)(9)(F)

A change is proposed to change the term medical "surveillance" to medical "services," to be consistent with the common use of the term surveillance. The purpose and necessity for this change is to provide clarity in the text.

Subsection (e)(3)

A change is proposed to substitute the term "employee medical records" for the term "records of medical surveillance." The purpose and necessity for this change is to be consistent with the common use of the term surveillance, and to be consistent with the text of this standard and with Section 3204 to which this subsection refers.

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Summary and Response to Oral and Written Comments

<u>Larry Wong, CIH, University of California Safety Manager, Environment, Health and Safety, Office of Risk Services, University of California, Office of the President, by letter dated August 21, 2008</u>

Comment #LW1: The University's primary concern with the proposed standard is that the standard does not clearly describe the "agents at risk." The statement of reasons mentions Exotic Newcastle Diseases, bovine TB, human cases of avian influenza resulting from exposure to wild birds and poultry, exposures to Q fever and other zoonotic diseases in research institutions, veterinary operations, laboratories, pet stores, and zoos. The relevance of some of these agents to California is not clear. Field operations at the University are under the oversight of safety committees including the Institutional Biosafety Committee, the Institutional Animal Care and Use Committee, Environmental Health and Safety Departments, and Veterinary Directors.

Response: Zoonotic aerosol transmissible pathogens are defined in subsection (a)(4) as those disease agents which are transmissible from animals to humans by aerosol and are capable of causing human disease. In the absence of any specific alert, diagnosis of disease, or quarantine or other disease control orders, the standard would require only that employers reduce potential exposures through the Injury and Illness Prevention Program (IIPP) and related measures such as sanitation or personal protective equipment. This is consistent with the use of biosafety committees and other institutional resources as described.

The Division has investigated occupational diseases contracted by both field and institution based researchers, including exposure to Q fever in sheep and exposure of field staff to hantavirus pulmonary syndrome.

The proposed standard relies upon the sentinel activities of the local health agencies, the California Departments of Fish and Game, Food and Agriculture, and Public Health, and the CDC and USDA to identify and provide notice of zoonotic ATP outbreaks that are of concern to California employers in general. The standard then requires the employer with occupational exposure thus established geographically or by activity, to implement additional appropriate control measures. The Board believes that this approach of instructing employers to be responsive to the health advisories of these agencies would be more effective than attempting to create a rigid regulatory regimen that might not be responsive to the fluid and rapidly evolving circumstances of a disease outbreak.

Please see response to comment #LW2 for further discussion of the application of the section in animal research facilities.

<u>Comment #LW2:</u> The standard does not use risk-based assessments as the basis for applying controls. The University uses risk assessment and adheres to the guidance provided by the BMBL 5th edition for Animal Biosafety Levels. In addition, the commenter asserts that "most

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strains of highly pathogenic avian influenza are not directly transmissible to humans unless there is a mutation or a co-infection with another vulnerable species such as pigs or horses."

Response: Currently, laboratory operations that conduct research with animals that may be infected with zoonotic ATPs are already required by Section 3203 to identify, evaluate, and control hazards related to those operations. The Board agrees that in animal research facilities in which live animals are kept (vivariums), the BMBL provides an appropriate risk assessment and control methodology. Therefore, a new subsection (a)(2)(F) directs those employers to perform a risk assessment and provide measures in accordance with the BMBL, which is incorporated by reference in subsection (a)(4). Where the risk assessment concludes that Animal Biosafety Level 3 or above practices are required, then the standard would also require employers to comply with the requirements of subsection (d), which addresses exposures to animals infected with zoonotic ATPs. The BMBL may also be used by any employer, including the field operations of the University, as a basis for developing their IIPP. The Board notes, however, that many employers covered by this standard would find that approach unnecessarily complicated.

Recent studies of avian influenza outbreaks in the Netherlands (H7N7) and Canada (H7N3) indicate that humans do, in fact, contract avian influenza directly from exposure to birds. (Tweed, Bosman). In at least one case this infection was fatal. As of February 2009, the World Health Organization reported that there were 408 human confirmed cases of H5N1 avian influenza, resulting in 254 deaths. Most H5N1 cases are attributed to direct human contact with birds.

Comment #LW3: The University understands the need to implement work precautions in field environments, especially where the absence of engineering controls and industrial ventilation may require the use of personal protective equipment and other measures specified in the biosafety plan. The absence of risk-based assessment will make compliance difficult. For example, requiring administration of vaccinations and medical surveillance in subsection (c)(2)(E) without further guidance presents numerous administrative difficulties, including handling declination statements.

Response: In the absence of a specific alert, disease control order, or disease control operation, this standard only requires that the employer take reasonable measures to identify, evaluate, and control zoonotic disease hazards in accordance with Section 3203 (IIPP), and other existing regulations. To clarify this, a sentence has been added to subsection (a)(2)(A). The need for personal protective equipment (PPE) must currently be assessed, in accordance with Article 9, and with Section 5144 (respiratory protection). This proposal creates no requirement for providing vaccinations unless there is an elevated risk, identified either by an alert pertinent to exposure to wildlife (subsection b), a disease control order such as a quarantine or movement restriction (subsection c), or an operation involving contact with animals infected with zoonotic ATPs, such as an operation to depopulate infected poultry (subsection d) or a laboratory in which animals are infected with zoonotic ATPs that require aerosol controls under BMBL (ABSL-3 or above). In terms of vaccinations of employees who are exposed to infected animals in a

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laboratory setting, employers would be required to follow recommendations of the BMBL, which is the standard reference in these environments.

The section cited by the commenter ((c)(2)(E)) refers to operations in workplaces that are subject to a quarantine order, movement restriction, or other disease control order, such as would exist if a zoonotic avian influenza outbreak were to occur. At that time, public health authorities may recommend preventive medical measures such as seasonal influenza vaccine or prophylaxis with an antiviral such as oseltamivir (CDC, 2006). Limited experience in controlling exposure to avian influenza has found that providing these measures to employees reduces the risk of disease. (Tweed, Bosman).

The Board does not agree that requiring appropriate use of vaccines as an exposure control measure under the limited circumstances addressed by subsections (b), (c) and (d) of this standard would result in an overly burdensome administrative task. Vaccines are one of the most effective preventive measures for disease. Experience in health care and other industries with hepatitis B vaccine and other vaccines demonstrates that the benefit that can be achieved by the appropriate use of vaccines far outweighs the administrative costs. Declination statements are an important mechanism for encouraging employees to accept a vaccine, and are also a mechanism which can be used to ensure that the vaccine is actually offered to employees.

Comment #LW4: The commenter asks whether the statement in the rulemaking file that subsection (b) would establish specific requirements for employers with operations involving the sampling or capturing of potentially infected wildlife, or the collection and disposal of dead animals for which an alert has been issued, means that this standard does not apply in the absence of such an alert. Much of the field work conducted by the University of California in its field locations involves land management and research with animals in natural habitats, where the intent is not to introduce hazardous organisms. Employees are given safety briefings about vector transmitted disease and use of personal protective equipment, sanitation, and personal hygiene. The mandated requirements are a concern where the zoonotic agents are not specified, and it appears that the alerts may not be specific enough to determine if the provisions of the standard apply.

Response: Subsection (b) is intended to apply to employees who conduct surveillance of animal populations for the detection of a zoonotic disease of concern, and employees who conduct other activities in an area where a zoonotic ATP has been found in wildlife, and an alert has been issued. Typically, alerts will be issued by the California Department of Public Health, however, alerts may also be issued by the local health officer, which would apply only to their area of jurisdiction, or the California Department of Fish and Game or the California Department of Food and Agriculture. National agencies may also issue alerts. When these alerts are issued, they specify the area of concern, which may be limited to a small region or which may apply to the state or a larger portion of the United States, such as may be anticipated if there is detection of H5N1 avian influenza among migratory birds in North America. In response to comments, the language of subsection (a)(2)(B)2 has been modified to clarify that the alert must be applicable to the employer's operations. Examples are provided which include the geographic area and the

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species or type of animal. The word "public" has been added to the definition of the word "alert" to clarify that alert refers to a public announcement regarding a zoonotic disease hazard. The definition of "alert" has also been modified to include that the announcement or notification must pertain to a "detected zoonotic ATP" hazard.

Comment #LW5: Proposed subsection (d)(6) is of concern because it seems to exceed the requirements of the California Medical Waste Act. Does this subsection mean that every field site must have an autoclave or get a permit for an approved disinfectant, or that the waste must be transported back to a permitted facility?

Response: Proposed subsection (d)(6) requires that remains of "animals infected with zoonotic ATPs" be disposed of in accordance with the "applicable standards of the California Environmental Protection Agency and the United States Environmental Protection Agency." Subsection (a)(4) defines the term "animals infected with zoonotic ATPs" as those animals that have been diagnosed with a zoonotic ATP infection through testing or manifest the clinical signs and symptoms thereof, or animals that have been identified by the agencies responsible for animal health as requiring isolation, quarantine or destruction due to suspected or confirmed infection. These are not animals that are typically encountered in field operations, which would be covered by subsection (a)(2)(A), or if there is an applicable alert, subsection (b).

Further, this subsection only requires that the wastes from the operations conducted under subsection (d) be disposed of in accordance with the "applicable" Cal/EPA or EPA standards. Environmental regulations, other than the Medical Waste Act may apply to the wastes generated by these operations. This subsection does not create new requirements for the disposal of this waste. It only requires that the applicable regulations be complied with for the purpose of protecting employees from exposures that may result from the improper disposal of this waste. If environmental regulations permit the disposal of this waste as solid waste, this subsection creates no further requirement.

<u>Comment #LW6:</u> Subsection (d)(8) would require ongoing surveillance for signs and symptoms of zoonotic diseases as recommended by the PLHCP. This is very difficult to observe since many pathogens have simply cold and flu-like symptoms as the initial sign of illness. Does this mean that anyone displaying **any** symptoms as if he or she had occupationally acquired a zoonotic disease?

Response: Subsection (d)(8) applies only to operations involving contact with animals infected with zoonotic ATPs as discussed in response to comment #LW5. Therefore, the medical surveillance is the surveillance deemed appropriate by the PLHCP in regards to the specific operation. For example, an operation involving the eradication of poultry infected with a zoonotic avian influenza would be required to have medical surveillance for symptoms of avian influenza, and for any other zoonotic pathogens the PLHCP or public health officials determine is necessary. An operation involving eradication of cows infected with bovine TB would have medical surveillance appropriate to that operation. (Medical surveillance in animal research

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laboratory operations would be covered by the applicable sections of the BMBL based on the risk assessment, and would be specific for the pathogens of concern.)

<u>Lawrence Gibbs, CIH, Associate Vice Provost, Environmental Health and Safety, Stanford</u> University, by letter dated August 13, 2008

<u>Comment # LG1:</u> Many research operations are afforded protection from zoonotic hazards by requirements or guidance provided by the National Institutes for Health (NIH) and the Centers for Disease Control (CDC). Penalties for failure to follow the NIH requirements include the potential loss of federal research funding, a penalty far more significant than the Cal/OSHA penalties to an institution. This makes the proposed regulation unnecessary.

Response: While many animal research facilities choose or are required to comply with recognized guidance documents, the Board believes that Cal/OSHA regulations are necessary to ensure that employers, employees and other interested parties are aware of specific requirements that are necessary to protect employees. The California Labor Code provides a mechanism by which employees can seek to get hazardous conditions in their work place corrected in a timely manner, and the responsibility of Cal/OSHA to protect employees cannot be delegated to a contract between the employer and a third party. Further, periodic contract audits do not serve the same function. In the Division's experience enforcing other regulations in laboratory environments, the existence of NIH or CDC guidelines, even when incorporated into contractual relationships does not always ensure compliance with occupational safety and health standards. A change is proposed to require that vertebrate animal research facilities comply with the BMBL, which is the generally referenced standard by NIH and CDC. Please see response to comments #LW2 for further discussion.

<u>Comment #LG2:</u> Research operations are already required to comply with existing Cal/OSHA regulations including the Injury and Illness Prevention Program and Bloodborne Pathogen Standards. The additional, and in some cases redundant, requirements of the proposed standard will impose an administrative burden that is not justified by the foreseen benefits.

Response: Under normal circumstances, the proposed standard refers to existing requirements in Section 3203 (IIPP) and requirements relating to sanitation and personal protective equipment was designed to allow employers to build upon their existing IIPP. (Section 5193 only addresses experimental animals infected with bloodborne pathogens.) The Division has investigated employee exposures to zoonotic diseases, including Q fever and hantavirus pulmonary syndrome, in research settings. The Board believes that existing zoonotic exposures, as well as potential exposures such as avian influenza, create a need for a standard that addresses zoonotic ATP hazards, both in normal operations, and once there is a detected increase in risk.

In regards to research settings, a change has been proposed to require that animal research facilities comply with the risk assessment and control methods in the BMBL, which specifically addresses exposure to animals in Chapter V. In other work settings, such as field research or

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veterinary operations, employers may choose to use the risk assessment and control methodology in the BMBL to address the requirements in subsections (a)(2)(A).

Barbara Materna, Ph.D., CIH, Chief, Occupational Health Branch, California Department of Public Health, by written and oral comments received at the August 21, 2008, Public Hearing

Comment #BMaterna1: The commenter spoke and wrote in support of the proposal. The written comments stated the CDPH's strong support for proposed Section 5199.1 "as an important and necessary step to ensure" California's health care, public health and other workers at risk for contracting zoonotic ATPs have enforceable protections and that employers have a clear direction. The commenter stated the need for the standard has become more evident in recent years as workers in California and elsewhere have faced zoonotic ATPs such as bovine tuberculosis, SARS and Avian influenza. Health care workers, for example, were a large proportion of those infected in the SARS epidemic in Toronto. In California, the Occupational Health Branch and other programs of the CDPH have responded to many situations involving workers who have been exposed or potentially exposed to ATPs, including investigations of Q-fever at rendering plants, laboratory-acquired brucellosis, and exposures to bovine TB in slaughterhouse, laboratory and farm environments. The commenter noted the standard has been developed by a thorough and thoughtful process involving all potential stakeholders, and the commenter offered the resources of the CDPH towards assisting Cal/OSHA to develop necessary implementation tools and guidance for employers.

<u>Response:</u> The Board thanks the commenter for her support of this standard and the assistance provided by the CDPH in developing this standard.

<u>Charles Corsiglia, Manager of Veterinary Services for Foster Farms, by oral comment at the</u> August 21, 2008, Public Hearing

<u>Comment #CC1:</u> Dr. Corsiglia commended Division staff on their outreach to the animal industry in the development of this proposal and stated that much of the proposal had come from the animal industry.

<u>Response:</u> The Board thanks Dr. Corsiglia for his support for the effort that went into developing this proposal.

Bill Mattos, President, California Poultry Federation, by electronic mail dated August 21, 2008

<u>Comment #BMattos1:</u> The Federation supports the verbal comments made at the hearing by Dr. Corsiglia of Foster Farms. The Federation supports the fact that the USDA and the CDFA are the regulatory authority regarding disease outbreaks/eradication and nothing should be triggered unless there is a regional declaration by these agencies.

<u>Response:</u> Under normal circumstances, the proposed standard refers to existing requirements under Section 3203 (IIPP) and to current requirements regarding sanitation and personal

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protective equipment. A sentence has been added to subsection (a)(2)(A) to clarify that compliance with these requirements is all that is required unless employees participate in work operations identified in subsections (a)(2)(B) through (a)(2)(G). As the commenter recommends, additional requirements under subsection (c) are only triggered in regards to poultry and other farm animals, if the CDFA or USDA imposes a quarantine order, movement restriction or other animal control order. Additional requirements under subsection (d) are only triggered once animals are diagnosed with a zoonotic ATP infection (based on testing or clinical evidence) or are ordered destroyed by the responsible agencies, which in the case of agriculture are the USDA and CDFA. The Board agrees with the commenter that this is the appropriate response to take to control zoonotic ATP hazards to employees in agricultural establishments.

Anne Katten, MPH, Pesticide and Work Safety Project, and Cynthia Rice, Director of Litigation, Advocacy and Training, California Rural Legal Assistance Foundation, by letter dated August 8, 2008

<u>Comment #AK1:</u> The commenters urge the adoption of this proposed standard to protect from zoonotic aerosol transmissible diseases California employees who work with wildlife, farm and exotic animals, as well as those who will be on the front lines in animal disease outbreak response operations.

Response: The Board thanks the commenters for their support of the standard.

Comment #AK2: The subsection (a)(2)(A) provision for employers handling farm animals or untreated animal wastes to develop and maintain effective procedures for controlling employee exposure to airborne diseases of animal origin and to provide training in this area are requirements of critical importance. These requirements should be stand-alone rather than components of the employer's IIPP.

Response: In developing the proposal, Division staff noted several cases of employee illness that were related to a failure to address zoonotic ATP hazards under the employer's health and safety plan. Subsection (a)(2)(A) is intended to direct employers to existing requirements to address zoonotic ATP hazards, under the IIPP and standards relating to sanitation and personal protective equipment. This subsection clarifies what procedures and training must be developed by the employer. Although not creating any new requirements, this subsection is intended to notify the regulated public that hazards relating to zoonotic ATPs must be identified, evaluated and controlled. Although referring to Section 3203, it is a regulatory provision on its own, and is meant to provide a mechanism by which employers covered by this standard will address zoonotic ATP hazards. In that sense, it is a "stand-alone" provision.

<u>Comment #AK3:</u> Because a disease outbreak can appear suddenly and spread rapidly, the standard should require all farm animal handling operations to provide change rooms and showers in addition to frequent access to hand washing and sanitary facilities required in existing Cal/OSHA regulations; training should also specifically cover the right to ready access to sanitary facilities. For the same reason, the regulation should require employers to offer free

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medical evaluations to those workers handling farm animals or untreated animal products or waste who develop symptoms consistent with airborne diseases carried by the animals or animal products handled.

Such workers should also be offered seasonal flu shots and any other vaccination recommended by the CDC or CDPH or local health officers for persons at risk of airborne diseases transmissible by farm animals. Employees of farm animal handling operations rarely have health insurance and have extremely limited access to health care.

Response: The Board agrees that employers covered by this standard should plan for foreseeable zoonotic ATP related disease outbreaks. For each covered employer, this preparation may vary. Subsection (a)(2)(A) requires employers to establish, implement and maintain effective procedures to address the hazards of occupational exposure to zoonotic aerosol transmissible pathogens, and draws the attention of employers to applicable sanitation and biosecurity measures, that may include establishing change rooms and shower facilities, and certainly include providing the facilities currently required by Article 9, such as hand washing and toilet facilities. Similarly, an employer should determine whether personal protective equipment is necessary during routine operations. In the advisory process leading up to the publishing of this proposal, the necessity for requiring specific medical services or additional specific sanitation and control measures, in the absence of a detected ATP hazard, was not demonstrated and therefore those requirements are not included in subsection (a)(2)(A). The training provided under this subsection should address how employees would detect an outbreak of disease caused by a zoonotic ATP, and how the employee should respond.

If an employee becomes ill with symptoms consistent with occupational exposure to zoonotic ATPs, subsection (a)(2)(A) requires an employer to investigate the illness. If the disease is due to an outbreak of zoonotic ATP infection in animals to which the employee is exposed, then public health and animal health agencies should be notified, and other portions of the standard may be triggered.

Comment #AK4: The commenters support the requirement in subsection (d)(4) for elastomeric face piece respirators for enclosed workspaces where diseased animals are being handled, as studies have documented the difficulty for some to achieve reliable fit with filtering face piece respirators. However, a half mask facepiece respirator will not always provide adequate protection from zoonotic ATPs. Employers should be required to follow any CDC or CDPH recommendations for higher level respiratory protection for specific pathogens or animal handling operations. Employers should not be permitted to determine that respiratory protection is not needed based on objective evidence, unless that determination is subject to DOSH oversight and approval.

<u>Response:</u> Employers who are required to provide respiratory protection under this standard, must do so in accordance with Section 5144. This requires a respiratory protection program that includes selection procedures for respirators. The requirement in this standard to provide certain minimum levels of respiratory protection does not relieve the employer from the responsibility to

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ensure that this level of protection is adequate. California law prevents the Board from making references to possible future CDC and CDPH recommendations. At this time, there are no CDC or CDPH recommendations for these types of operations that exceed those included in this standard.

In regards to the determinations referenced in this subsection, the language has been changed to require employers to demonstrate through objective evidence that respirator use, or the use of the specified level of respiratory protection is not necessary. This clarifies that the employer must either comply with the stated requirements, or demonstrate through objective evidence that the respiratory protection is not necessary, and provides a mechanism by which the DOSH can evaluate that decision.

Comment #AK5: Subsection (d)(5)(D) regarding removal of warning signs from areas treated with toxic or asphyxiant gases should be revised from the current wording to read "does not exceed the permissible limits..." in order to provide adequate protection to workers who reenter the treated area for periods exceeding 15 minutes.

Response: The wording of the sign referred to in this subsection is "Danger – Do not Enter," and is intended to address an atmosphere that is immediately dangerous to life or health (IDLH). This corresponds to concentrations that are typically represented by ceiling or short-term exposure limits. Although it is not ideal, under some circumstances, employees may work in areas that exceed an eight-hour time-weighted average permissible exposure limit by using appropriate respiratory and other personal protective equipment. The intent of this subsection is to ensure that until the immediate danger from gases has been removed, no one may enter the area unless it is done under procedures for IDLH atmospheres. Therefore, the Board believes this wording is appropriate.

<u>Comment #AK6:</u> The commenters strongly support the requirements in subsection (d)(7) for decontamination facilities but think the exception should require an employer to demonstrate to the Division when change rooms and showers are not feasible. We find it hard to envision any 21st century situation in which change rooms aren't feasible and situations in which showers aren't feasible should be extremely rare.

<u>Response:</u> Because this provision is structured as an exception, employers who do not provide the required change rooms and showers must be able to demonstrate that they are not feasible, and must, in addition, provide effective measures for decontamination and changing clothes that protect employees from infectious materials.

<u>Jacqueline Nowell, Director, Occupational Safety and Health Office, United Food & Commercial Workers International Union, by letter dated August 14, 2008</u>

<u>Comment #JN1:</u> The UFCW represents 30,000 poultry workers in the United States, and 5700 in California. Protecting these workers who are exposed to animals and animal products or wastes

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that are known or suspected to be infected with zoonotic diseases, especially avian influenza, would be a positive step in preventing an epidemic of pandemic flu in the US.

Response: The Board appreciates the commenter's support for this standard.

<u>Comment #JN2:</u> In the experience of the UFCW, poultry catchers are not provided adequate training about the hazards of dead birds and the proper safety precautions to take; sometimes they are lied to about dead birds or given misinformation in English, while many such employees are Spanish speaking. Workers do not change their work clothes before going home and often eat on site. Other specific concerns about poultry catchers include:

- There are always sick birds but workers are not given training to recognize avian flu
- Masks' given are inappropriate for respiratory protection
- There is no soap on site
- Supervisors are uninformed
- There is no training or information about seasonal flu vaccine, so most employees do not take advantage of free vaccinations that are offered

Chicken "hangers" also have not received training on avian flu symptoms in themselves or birds and have not received free-of-charge vaccinations.

<u>Response</u>: The Board recognizes that there may be significant communications and training issues. Section 5199.1 provides a framework for improving employer compliance with existing requirements for training and communication, sanitation, and personal protective equipment.

Comment #JN3: Subsections (a)(1)(B) Scope and (a)(4) Definitions refer to USDA or CDFA inspections required under food safety regulations. The language in these two places should be clarified so that the word "passed" is not inferred to mean "pass" or "fail," but rather to a place or position on the processing line in a slaughter or processing plant at which a USDA or CDFA inspection has occurred.

Response: Subsection (a)(4) of the proposed standard gives the definitions for the abbreviations "USDA" and "CDFA," but the subsection does not include a definition for "passed." The term "passed" as used in the Scope of proposed 5199.1 ("...that have passed an inspection conducted in accordance with regulations of the USDA or CDFA") is directly referenced to USDA and CDFA regulations (which are to be found in 9 CFR Chapter 3, Part 301; 3 CCR Chapter 4, Article 1). Both agencies similarly define the term to mean that an animal product has completed an inspection and has been determined to be fit for human consumption in order to be considered to have "passed." The proposal has been modified to include the phrase "and has been determined to be fit for human consumption" in the two subsections identified by the commenter, to ensure that the use of the term "passed" is understood by the regulated public.

Comment #JN4: In subsection (c)(2)(C), the standard should prescribe at minimum a P100 filtering face piece respirator for entering a restricted area; as written the employer is permitted to choose an N95 respirator. Employers might not base their choice on the most recent research.

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For example, see the attached AFL-CIO comments on Section 5199 which include mention of recent research demonstrating N95 respirators are not sufficient to protect workers from aerosol transmissible disease; these AFL-CIO comments also give a rationale against the use of either N95 or N99 respirators.

Response: Although the AFL-CIO comments and the published articles they cite (See Lee, 2008, Balazy, 2006, Lee 2005, and Eninger, 2008) raise some question regarding the exact protection factor provided by N95 respirators against some sizes of particles, many questions remain. For example, it is not known what size particle must be captured by the respirator filter in order to prevent infection, as many pathogens are presented in a droplet or droplet nuclei, rather than as a naked pathogen. At this time, the National Institute for Occupational Safety and Health, and the Centers for Disease Control and Prevention, recommend the use of the N95 respirator. Some studies have found that N95 respirators provide effective protection against a range of particle aerosols. (See, for example, Coffey 2004, Lawrence, 2006). Therefore the Board has not determined at this time that a higher level of respiratory protection is necessary, other than in the conditions specified in other portions of this standard.

However, as noted in response to comment #AK4, when employees use respiratory protection under this standard, the use must be in accordance with Section 5144. This requires full compliance with Section 5144, including the employer's responsibility to have written procedures for selection of respiratory protection, and to select a respirator that provides adequate protection.

<u>Danielle Lucido, Staff Attorney, and Suzanne Murphy, Executive Director, Worksafe, by letter</u> dated August 21, 2008

Comment #DL1: While the commenters support the requirement in subsection (d)(4) for elastomeric face piece use in enclosed workspaces with diseased animals, there is concern that such respirators, particularly half-mask, will not always provide adequate protection. This subsection should include a requirement to provide the CDC or CDPH recommended level of protection, including levels of protection higher than the elastomeric face-piece if recommended. We further believe this subsection should give DOSH oversight of an employer determination that respiratory protection is not needed "based on objective evidence."

<u>Response:</u> See the response to comment #AK4.

Comment #DL2: While the commenters support decontamination facilities in section 5199.1(d)(7), to qualify for an exception an employer should be required to document to the Division that change/shower rooms are not feasible.

Response: See the response to comment #AK6.

<u>Comment #DL3:</u> As workers who handle farm animals often don't have medical insurance and have limited access to health care, employers should be required to provide free medical

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evaluations if workers handling farm animals or untreated animal products and wastes develop symptoms consistent with zoonotic airborne disease. Also employers should be required to provide seasonal flu shots and other shots recommended by CDC, CDPH or local health officers.

Response: See the response to comment #AK3.

Elizabeth A. Treanor, Director, Phylmar Regulatory Roundtable, by written comments dated August 21, 2008, and oral comments received at the August 21, 2008, Public Hearing

<u>Comment #ET1:</u> The scope of the proposed section is too broad, and includes nearly all employers, rather than focusing on employers with moderate or high risk of employee exposure to zoonotic aerosol transmissible pathogens. This comment also refers to comments summarized as #ET5 and #ET6.

Response: Absent a specific noticed hazard of exposure to zoonotic ATPs, the proposal creates no new requirements for employers. Subsection (a)(2)(A) restates existing requirements that employers address exposures to diseases that may be transmitted by animals through their injury and illness prevention program (IIPP), and references existing requirements for sanitation and personal protective equipment. Animals and their wastes may contain pathogens that can cause significant human disease. Further, animals may be an important means of introducing emerging pathogens to humans. It is important that simple, common sense measures of controlling risks, such as minimizing airborne dusts, avoiding direct contact through use of gloves, and handwashing after contact be practiced when employees do activities such as picking up dead birds. Therefore the Board does not believe that the scope of this proposal is too broad. Please see response to comments #ET2 and #ET7 for further discussion of this issue.

<u>Comment #ET2:</u> The commenter is concerned that a "wide range" of requirements are placed on employers for which there are no resources to fulfill, particularly for incidental exposures. This comment refers to a comment summarized as #ET7 below.

Response: Comments received indicated a need to further clarify how this section will apply to exposures described by the commenter as "incidental," such as the picking up of dead birds by utility workers. Therefore several changes have been made to subsection (a)(2)(A). These changes are meant to clarify that all employers covered by the standard must generally evaluate zoonotic ATP hazards, and take certain common sense measures to control the hazard. Examples of these types of measures include instructing employees to avoid direct contact with animals or their remains, and to minimize dusts created when moving them. The term applicable has been inserted to explain that requirements for biosafety measures and personal protective equipment only apply in those situations as and when they are necessary to control a specific exposure. A sentence has also been added to explain that absent other conditions identified in subsections (a)(2)(B) through (a)(2)(G), employers may meet their obligations under this section by complying with subsection (a)(2)(A) only. Additional explanation has been added to the definitions of "alert" and "biosecurity" that further clarify that higher levels of protection are not

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typically required unless other triggering circumstances exist. Please also see response to comments #ET1 and #ET7.

<u>Comment #ET3:</u> It would be helpful for employers to know the details of "deficiencies" found by the Division and the circumstances of the inspections referred to in the initial statement of reasons (ISOR).

<u>Response</u>: Division staff state that in all cases reviewed by the Division, although the employer may have had an IIPP, the program, with the exception of some general training in some cases, did not address the zoonotic disease hazards. The Division plans to involve employers, employee representatives and other interested parties in developing guidance materials for implementing this regulation that will be specific to the industries involved.

<u>Comment #ET4:</u> Tracking specific federal and state alerts that may apply to wildlife in an employer's geographic area is "fraught with uncertainty" and may be burdensome. The Department of Industrial Relations' Communications office or other media group should provide outreach to employers warning of such alerts.

<u>Response</u>: A modification has been made to the definition of "alert" to clarify that the announcement must be "public." Further, the definition explains that the "alert" must be regarding the detection of a zoonotic ATP hazard. The California Department of Public Health has plans in place to announce any zoonotic ATP hazard, such as avian influenza through broad media outreach. Although the CDPH has the lead responsibility for these notifications, the local health officer may initiate one as well, as may several of the other referenced agencies.

Comment #ET5: Subsection (a)(1)(A)8 states "Operations involving the cleanup, decontamination, or disinfection of areas potentially contaminated with zoonotic aerosol transmissible pathogens." Virtually all employers are faced with the potential need to remove dead wildlife or birds nests, or perform operations in areas in which wildlife reside. "These employers currently are required to establish health and safety procedures and train their employees under Section 3203." These incidental exposures do not involve an elevated risk. Further, some employers would like clarification that this section does not impose an obligation on them to conduct testing for pathogens on dead animals found at workplaces. The commenter suggests returning to language in a draft circulated to participants in the Division's advisory process dated 2/8/07.

<u>Response</u>: Subsection (a)(1)(A)8 was intended to address operations that involve the clean up of areas potentially infected with zoonotic ATPs, such as areas in which infected animals had been kept and/or destroyed. To clarify this intention, the wording of subsection (a)(1)(A)8 has been changed to read "Zoonotic ATP incident response operations as defined below." A definition for "zoonotic ATP incident response operations" has also been proposed.

The commenter noted that incidental clean up of wildlife, including wastes, is currently addressed through Section 3203. Subsection (a)(2)(A) continues that approach. Additional

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measures are only required when there is a triggering condition that increases the potential of employee exposure to zoonotic ATPs. Please see response to comment #ET2 for additional discussion of changes proposed to this subsection.

The commenter distinguishes between incidental exposures and exposures that require control measures. However, it is not actually possible to always determine what exposures may create a hazard for employees, because that differs based on factors such as the specific pathogen and the exposure conditions. Therefore, in the absence of a specific elevated level of hazard, the proposed standard requires that employers take reasonable measures to reduce risks under the IIPP, as described by the commenter.

Division staff note that the advisory committee draft referred to by the commenter was circulated for feedback via e-mail and the Division's website, and was modified in response to comments received from various sources.

<u>Comment #ET6:</u> Subsection (a)(1)(A)8 should be deleted for the reasons stated in comment #ET5 or revised to exclude incidental exposures that do not pose a significant risk to employees.

Response: Please see response to comment #ET5.

<u>Comment #ET7:</u> The language in subsection (a)(2)(A) may be construed to require measures such as traffic control, disinfection and isolation in all situations. The commenter suggested inserting wording into this subsection to clarify that these measures are only required when appropriate. The commenter also suggested that the term "where appropriate" be used to modify training requirements. Also, it is unclear what the difference is between the biosecurity measure of disinfection and sanitation.

<u>Response</u>: The word "applicable" has been inserted into this subsection in regards to biosecurity procedures and PPE. In addition, the definition of biosecurity has been expanded to provide more guidance on what is meant by biosecurity, and how it relates to sanitation. These two changes will clarify the intent of this section. Biosecurity can be thought of as expanded sanitation measures that are specifically designed to prevent transmission of pathogens via a person, animal, or material to another animal, person or area. Because controls such as using boot washes between barns are not typically thought of as "sanitation," this proposal uses the term "biosecurity," which is a standard term used in animal husbandry.

Comment #ET8: The alerts triggering additional control measures referenced in subsection (a)(2)(B) should be specific regarding the type of wildlife involved, and should take into account the potential for this wildlife to be infected with zoonotic ATPs and the geographic area covered by the alerts. Subsection (a)(2)(B)2 should be revised to read that an "alert regarding the potential for occupational exposure to aerosol transmissible zoonotic infection has been issued by the CDC, CDFA, CDFG, USDA, or USDOI."

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Response: As originally noticed, the definition of the term alert in subsection (a)(4) states that the alert may be issued for a specific geographic area or species. The word "public" has been added to the definition to address concerns that employers may not be aware of an alert, as mentioned in response to comment #ET4. The language in the definition has also been modified to clarify that an alert is a public announcement or notification regarding a "detected zoonotic ATP." Further, subsection (a)(2)(B)2 has been modified to indicate that the alerts triggering additional requirements are those that are applicable to the employer's operations based on the conditions specified in the alert, e.g. the geographic area and species or type of animal.

In regards to the specific suggestion that the additional control measures in subsection (b) be triggered by an alert from the CDC, CDFA, CDFG, USDA, or USDOI for "occupational exposure to aerosol transmissible zoonotic infection," it is not within the mission or expertise of these agencies to address occupational exposure, which is assigned in California to Cal/OSHA. The public alerts issued by these agencies may not specifically address occupational exposures, and the Board cannot impose upon these agencies the duty to define them or to prescribe protective measures for employers to follow.

<u>Comment #ET9</u>: In regards to subsection (b)(3)(B)3, which requires that employees use respirators when "there are animal-related dusts in the environment that are reasonably likely to be an aerosol infection hazard to employees," it appears that respirators would be required in all circumstances for wildlife collection and disposal activities, even those conducted in well-ventilated outdoor environments. The commenter recommends that the language be changed to read, "there are <u>excessive</u> animal-related dusts <u>in an outdoor area or animal dusts in an enclosed or indoor area</u> that are reasonably likely to be an aerosol infection hazard to employees."

Response: Requirements in subsection (b) are only triggered when an alert has been issued, that is applicable to the employer's operation, as discussed in response to comment #ET8. So it is not the case that respirators would be required in all circumstances for wildlife collection and disposal activities. As noticed, when there is an applicable alert, subsection (b)(3) requires the use of a respirator at least as effective as an N95 filtering facepiece respirator, in accordance with Section 5144, under three circumstances: 1. when there is in increased potential of exposure to infectious aerosols, such as when handling animals in an enclosed or indoor area, 2. when responding to a mortality event involving a significant number of animals, or 3. there are animalrelated dusts in the environment that are reasonably likely to be an aerosol infection hazard to employees. The first two circumstances identify conditions which are likely to increase exposures to infectious aerosols. The third requires the employer to determine whether the dusts in the environment are reasonably likely to be an aerosol infection hazard to employees, and if that is the case, to require the use of respirators. As suggested by the commenter, the ventilation in the area is one component of determining whether animal related dusts are reasonably likely to be an infectious disease hazard to employees. There are other conditions that should be considered including the work activity to be conducted, the potential route of exposure and the likelihood that viable pathogens would be present. If the work activities of an employee do not create a significant near-field exposure to pathogen-containing dusts, then the general ventilation in the environment may not be sufficient to control exposure. In other circumstances, the use of

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dust control methods may reduce the need to use respirators. For that reason, the Board declines to further elaborate on this condition.

Kevin Bland; Terry Thedell, Health and Safety Advisory, Sempra Energies; Larry Pena, Southern California Edison; Bo Bradley, on behalf of the Associated General Contractors of California; Bruce Wick, CalPASC; and John Vocke, Attorney, Pacific Gas and Electric Company, by oral comments at the August 21, 2008, Public Hearing.

<u>Comment #KB1:</u> The commenters stated that they support the comments prepared by Elizabeth Treanor.

Response: See responses to comments #ET1 through #ET9.

William T. Fujioka, Chief Executive Officer, and Steven E. NyBlom, Manager, Risk Management Branch, County of Los Angeles, by letter dated August 21, 2008

<u>Comment #WF1:</u> Proposed Section 5199.1 would comprehensively regulate the preparation and response by employers to threats from zoonotic aerosol transmissible diseases and would also place a significant financial burden on local governments. The state needs to show that the targeted diseases are rising in incidence. A statewide cost benefit analysis of this proposal is necessary.

Response: In the absence of a specific triggering condition, such as an applicable alert, the standard does not impose any new requirements upon any employer. Subsection (a)(2)(A) simply requires employers to address zoonotic ATP hazards under their injury and illness prevention program, and comply with existing requirements for sanitation and personal protective equipment. When an alert for a zoonotic ATP in wildlife is issued, then employees who are exposed to the wildlife subject to the alert, must be provided with some additional protections. These protections are consistent with recommendations of state and federal public health agencies to protect employees against zoonotic ATPs, and include cost-effective exposure reduction measures such as the use of inverted bags to collect dead birds. Under alert conditions, respiratory protection is required if dusts would pose a hazard to employees. This requirement creates no new costs, as respirators would be required under existing Section 5144. Subsections (c) and (d) are triggered by the existence of a zoonotic ATP hazard that is either diagnosed or addressed by infection control orders of government agencies. It is unlikely that county employees would play a significant role in either operation, and if they do, the level of protection that is provided by this standard is necessary to protect them from serious illness or other harm.

This standard therefore represents an appropriate and cost-effective method of addressing these hazards. The commenter has provided no specific information that causes the Board to reevaluate the cost estimates of the proposed standard contained in the rulemaking file. Further, the standard places no mandate on local agencies, other than complying with requirements as an employer.

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Some local jurisdictions may have operations that are specifically covered by subsections (c) or (d), but local government operations involving raising livestock, poultry, or other animal husbandry operations are generally typically limited in nature. Where local governments conduct these operations, the proposed standard would require the same compliance that would be expected from private operations. The requirements that apply to these operations have been based upon the contingency plans developed by CDFA with industry, and the experience that other states or countries such as Canada have had in dealing with outbreaks of zoonotic disease. The proposed standard thus would require that outbreaks are handled with methods that have been demonstrated to provide protection for the employees.

Terry Thedell, Ph. D., CIH, CSP, Health and Safety Advisor, San Diego Gas and Electric, by written comments dated July 31, 2008, and oral comments received at the August 21, 2008, Public Hearing

Comment #TT1: The scope of Section 5199.1(a)(1)(A)8 should not include the occasional encounter and cleanup of wild animal nests and wastes, the sort of encounter that occurs during his utility company's operation of 150 building facilities, over 75 remote telecommunication sites, and hundreds of auxiliary equipment substations across southern California. Clearing of occasional nests and/or "droppings" could involve a zoonotic aerosol transmissible pathogen, but the commenter believes that their current protective measures and investigation of occupational injuries and illness in their Injury and Illness Prevention Plan provides sufficient protection for these incidental occupational exposures. The commenter suggests that an exception be provided that states "Employers with facilities (i.e. buildings, warehouses, and outdoor structures) that may temporarily harbor wild animal nests with only incidental employee exposures are exempt from this section as they are subject to provisions of Section 3203." In response to questions from the Board, the commenter also stated that his company has procedures in place to avoid employee exposures to zoonotic aerosol transmissible diseases, and that the only pathogen which has been at issue is hantavirus. The commenter was also asked whether his company has procedures in place to keep track of other alerts that may be of concern to employees. The commenter responded that they watch things as they evolve, but to date have only encountered hantavirus.

Response: The operations described are included within the scope of subsection (a)(1)(A)1, and in the absence of an applicable alert, only the requirements of subsection (a)(2)(A) would apply to these operations. This subsection has the effect of requiring employers only to comply with existing Section 3203, and existing requirements regarding personal protective equipment and sanitation. If an alert is issued regarding the detection of a zoonotic ATP by agencies monitoring the infectious disease status of wildlife, then operations to which the alert applies would be required to implement the additional control measures in subsection (b). These are simple measures such as use of inverted bag techniques for picking up dead animals that provide an additional layer of protection, when there is a specific zoonotic threat.

The commenter appears to have read subsection (a)(1)(A)8 in relationship to subsection (d), as requiring a much higher level of precautions for the types of operations described in this

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comment. Subsection (a)(2)(A) has been modified to include a sentence that clarifies that in the absence of the conditions described in subsections (a)(2)(B) through (a)(2)(G), only the general IIPP, sanitation, and applicable PPE and biosecurity procedures (if any) apply. Subsection (a)(1)(A)8 has been rewritten to refer to zoonotic incident response operations, which are defined in subsection (a)(4). These are operations typically undertaken under the leadership of the California Department of Food and Agriculture, the United States Department of Agriculture, or other governmental agencies, to control an outbreak of a zoonotic aerosol transmissible infectious disease. These changes should clarify the relationship of this standard to routine clean up and disposal of occasional dead animals or their remains or wastes, which are only required to be addressed through existing IIPP, PPE and sanitation requirements.

Please see comment #ET1 for additional response regarding this issue.

Larry Pena, Southern California Edison, by oral comments received at the August 21, 2008, Public Hearing

Comment #LP1: Southern California Edison (SCE) has a large number of structures that may be affected by this proposal, particularly in regards to avian aerosol transmissible diseases. In particular, subsection (d)(1)(C)4 addresses personal protective equipment, and this equipment is a cause of concern in regards to safety around electrical equipment, and may also contribute to heat related illness. He is concerned that the use of full-body protective equipment, consisting of a synthetic plastic material when climbing wood structures for the sole purpose of removing a bird's nest could cause or exacerbate heat illness. There are situations in which for the sake of reliability and continuity of electrical service, employees have to remove birds' nests and sometimes, dead birds from structures. Wearing this personal protective equipment may also conflict with the high voltage safety orders which require the use of material that is not synthetic, because it is required to be non-conductive. Board Member Frisch asked the commenter to describe alternative methods of personal protective equipment that SCE has in place to protect employees from zoonotic airborne infectious diseases that would provide equivalent safety. The commenter stated that SCE's research does not indicate that there is disease transmission between wild birds and human beings. Dr. Frisch responded that beyond avian influenza, there is plenty of evidence and literature to indicate transmission of diseases from animals, including some avian species, to humans. He again asked what equivalent measures SCE has in place that would provide equivalent safety. The commenter responded that SCE uses a chlorine-water mixture to wet down a nest or nesting area, then removes the material using either tools or protective gloves, inserts them into a bag and disposes of them.

Response: Subsection (d) applies to operations involving the handling, culling, transporting, killing, eradicating, or disposing of animals infected with zoonotic ATPs or the cleaning and disinfection of areas used, or previously used, to contain such animals or their wastes. The term "animals infected with zoonotic ATPs" is defined in subsection (a)(4) to mean "Animals that (1) have been diagnosed with a zoonotic ATP through recognized testing methods or (2) meet the clinical definition of a suspect case of infection with a zoonotic ATP or (3) have been identified

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by the CDFA, CDFG, USDA, or USDOI as requiring isolation, quarantine, or destruction due to suspected or confirmed infection."

The operations described by the commenter (removal of wildlife or associated debris such as nests associated with the maintenance of structures or utilities), are not included within the scope of subsection (d). Under normal conditions, these operations are addressed in subsection (a)(2)(A), which requires the employer only to address potential exposures through its IIPP and requirements related to sanitation and personal protective equipment. These procedures may include the types of controls described by the commenter in response to Dr. Frisch's questions. If employees are exposed to a wildlife species for which an alert has been issued by identified governmental agencies, then the provisions of subsection (b) are triggered. These provisions do not typically include the use of the type of personal protective equipment described by the commenter.

The Board has made several changes in the proposal in order to clarify the application of this section. Please see the response to comments #ET1 through #ET9 and comment #TT1 for further discussion of these issues.

Bo Bradley, Association of General Contractors, oral comments received at the August 21, 2008, Public Hearing

<u>Comment #BB1:</u> The commenter stated that she agreed with the comments provided by Elizabeth Treanor. She stated that the construction industry does have procedures in place to address the disposal of dead animals.

Response: Please see response to comments #ET1 through #ET9.

John Vocke, Attorney, Pacific Gas and Electric Company (PG&E), by written comments dated August 20, 2008, and oral comments received at the August 21, 2008, Public Hearing

Comment #JV1: The commenter stated that hearing from Len Welsh, Chief of the Division of Occupational Safety and Health, that under normal circumstances the utility industry is covered by subsection (a)(2)(A) of the proposal, not other subsections, allays some of his concerns regarding the scope of the proposal. He stated that in addition to dealing with birds encountered at their facilities, PG&E also has an avian protection program that is meant to mitigate some of the impacts of utility operations on threatened and endangered species. The proposed standard could have a negative impact on that program.

PG&E employees have "incidental contact" with various types of wildlife while reading meters, making repairs, re-lighting pilots at customer facilities including basements, attics and crawlspaces. In this contact, they may encounter live or dead animals and/or their droppings or nests. Employees also handle dead birds in compliance with Special Use Permits from the United States Fish and Wildlife Service and the California Department of Fish and Game. They may move bird nests in order to prevent electrocutions of endangered species. These activities are

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infrequent and involve short periods of contact with the animal. The Avian Protection Plan is intended to reduce risks to migratory and threatened or endangered species, under a Federal Fish and Wildlife permit. The imposition of a "full panoply of biosecurity measures," would detrimentally effect these operations.

Although the ISOR and the Informative Digest refer to a graduated system of controls based on the nature of the exposure, type of work setting, and level of risk, the regulation goes beyond the stated purpose and covers "incidental, low-risk" work situations. Proposed subsections (a)(1)(A)1 and (a)(1)(A)8 would apply to PG&E activities involving the transportation or disposal of wild birds or other wildlife, or the cleanup of an area "potentially contaminated" with a zoonotic aerosol transmissible pathogen.

Response: In the absence of a specific alert issued by the authorized government agencies, this proposal (subsection (a)(2)(A)) refers employers to existing requirements under Section 3203 (IIPP) and sanitation and personal protective equipment regulations. Subsection (a)(2)(A) has been modified to clarify that absent triggering conditions as described in subsection (a)(2)(B) through (a)(2)(G), all employers are required to do is to comply with existing requirements under Section 3203 in relation to zoonotic ATP hazards, and to provide for sanitation, and for biosecurity and PPE as necessary. Further, the definition of "biosecurity" has been expanded to explain the intent of these procedures, and to clarify that picking up of occasional dead animals or associated debris such as nests, in the absence of an alert, does not typically require biosecurity beyond basic sanitation. In regards to exposures to occasional dead animals and associated debris, there is no requirement for a "full panoply" of biosecurity measures, such as might exist on a quarantined farm or during eradication of an infected animal population. The commenter provided no specific information regarding how the proposed standard would adversely impact wildlife protection programs. In the absence of a specific alert, the proposed standard provides the employer with wide latitude regarding how it will protect employees from zoonotic disease hazards in wildlife under their IIPP. It does not, for example, require any specific activity such as the removal of nests or other wildlife habitat. Alerts requiring increased levels of protection from wildlife will be issued by the agencies charged with protecting wildlife in California including the USDOI and the CDFG. This will support consultation with these agencies regarding existing wildlife protection programs in the event of such an alert.

Comment #JV2: The scope of the regulation has been expanded from the final draft dated February 2007, from the Advisory Committee by removing the term "occupational exposure" from subsection (a)(1) as a consideration for the operations/facilities/service categories listed in the scope. The reason for eliminating this term is not explained in the ISOR. Removal of this term places virtually all operations involving the management, capture, sampling, transportation or disposal of birds or other wildlife under the terms of the proposed standard. Research on zoonotic diseases does not support the need for protective measures for every encounter with animals that could potentially carry a disease which could be aerosol-transmissible to humans. The CDC document on hantavirus recommends that people who frequently handle or are exposed to rodents use enhanced precautions such as gloves, respirators and other similar devices. In the same document, it also states, "Insufficient information is available at this time to

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allow general recommendations regarding risks or precautions for persons in the affected areas who work in occupations with unpredictable or incidental contact with rodents or their habitations. Examples of such occupations include telephone installers, maintenance workers, plumbers, electricians and certain construction workers."

Another issue with defining high exposure risk situations occurs in subsection 5199.1(a)(1)(A)8. The commenter states that because this provision was not found in the scope of the February 2, 2007, Advisory Committee draft it "thus was not discussed during the Advisory Committee process." The commenter believes this reference to potentially contaminated areas is too broad. The commenter differs with the statement in the ISOR that employees who decontaminate or disinfect areas in which contaminated materials such as wastes may be present are potentially exposed to zoonotic ATPs such as avian influenza and bacteria which grow on organic matter. The commenter stated that a "potentially contaminated area does not fit the stated purpose of addressing high exposure risk scenarios."

<u>Response</u>: The Advisory Committee draft, dated February 2007, was circulated for feedback among participants in the advisory process and on the web. The issue of addressing response operations to outbreaks of zoonotic infection, including the depopulation and clean up of infected animals, was a part of various discussions in the advisory process and can be found in the minutes of the May 19, 2006, Advisory Committee meeting. Further, the notation with the posting of the draft clearly states that it is not a rulemaking proposal. As with other advisory drafts, it was not included in the ISOR; however all meeting minutes are available online and are included in the rulemaking package.

A number of comments have been received regarding the intended meaning of subsection (a)(1)(A)8. Therefore, this subsection has been reworded to specifically address "Zoonotic ATP incident response operations." These operations are further defined in subsection (a)(4) as "Operations conducted to control an outbreak of an animal disease involving the destruction and/or disposal of animals infected with zoonotic ATPs as defined above, and the clean up, decontamination and disinfection of areas and equipment associated with the infected animals or their remains." "Animals infected with zoonotic ATPs" is defined in subsection (a)(4) to include animals determined to have zoonotic ATP infection, either by testing or clinical signs, or animals identified as requiring quarantine, isolation, or other disease control measures, due to potential zoonotic ATP infection, by the responsible government agencies. The previous language referring to "areas potentially contaminated with zoonotic aerosol transmissible pathogens" has been removed.

The requirements of subsection (d) are only triggered by exposure to "animals infected with zoonotic ATPs." Most employers will only be covered by the requirements of subsection (a)(2)(A), which applies to contacts employees have with animals, their remains, or associated debris. A sentence has been added to subsection (a)(2)(A) to clarify this. This subsection requires employers only to address these exposures through their IIPP and to provide applicable personal protective equipment and biosecurity measures, as well as meet sanitation requirements. The circumstances necessary for people to contract zoonotic ATP infections differ based on the

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> pathogen or other factors. For example, although most human cases of H5N1 are related to exposures to domestic poultry, other cases have resulted from relatively short exposures to feathers and debris from dead animals. Other diseases can be transmitted from what may be called "incidental" contact with soils or animal wastes (CDC 2004, Soliva 2001, US Army 1992). Therefore, it is necessary that all employers whose employees contact animals take basic measures to assess the risks, and train employees on how to protect themselves against pathogens animals or their wastes may harbor. Employers may need to instruct employees on how to recognize situations that require personal protective equipment or use of dust minimization techniques. For example a utility may need to train employees working in counties in which hantavirus is present in deer mice of actions they should take if they find a large quantity of mouse droppings in an intermittently occupied field facility or to take extra precautions where there are unusual accumulations of bird or bat droppings. Similarly, employees encountering a large number of dead wild birds may need to take additional protective measures, if the cause of death is not known. The purpose of including a broad range of exposures to animals in the scope of the section is to provide clear notice to the regulated public that these hazards exist. Subsection (a)(2)(A) then requires employers who determine that there is potential exposure to zoonotic ATPs to address these exposures through their Injury and Illness Prevention Program (IIPP). Circumstances that increase the risk to employees, such as the issuance of an alert regarding detected zoonotic ATP infection in wildlife or a quarantine order or movement restriction by agriculture agencies, require increased levels of protection under this standard.

> Comment #JV3: Subsection (a)(2)(A) would require all employers with facilities or services listed in the scope to establish procedures in accordance with Section 3203. Every employer within the scope would have to write IIPP procedures for any employee exposure to zoonotic ATPs. This should be limited to occupational exposure. The CDC does not recommend personal protective equipment and biosecurity for all exposures.

<u>Response</u>: This section would require every employer listed within the scope to evaluate exposures and address them through its IIPP. Many commenters have stated that they already do that. Subsection (a)(2)(A) has been modified to use the term "applicable" in regards to biosecurity and the use of personal protective equipment. This modification should clarify that employers who have operations that involve contact with animals are only required to provide the measures that reasonably apply to the situation. Other changes to subsection (a)(2)(A) are discussed in response to comments #ET1, and #JV2.

Comment #JV4: Subsection (a)(2)(B)2 has unintended consequences for incidental exposure by using an "alert" issued by various listed agencies to trigger additional written procedures. "Alert," as defined in the proposal is an announcement or notification. "This could be interpreted as any fact sheet about a zoonotic disease in wildlife issued by any of the listed Federal or State agencies." Further, the alert is not limited to zoonotic ATPs. "For PG&E, electrical workers complying with our Avian Protection Program, who must collect and dispose of an occasional electrocuted raptor in a remote work site in the Sierras or a facilities worker who must pick up a dead pigeon in front of a building, or a gas serviceman who must move a mouse nest under a

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customer's home, must now be suited up in Tyveks with gloves and at least an N95 filtering facepiece respirator to perform any of these tasks if any listed agency has a fact sheet on avian influenza, psittacosis or hantavirus."

Response: As proposed, the word "alert" is defined in this section as "an announcement or notification by a local health officer, or California or federal agency, regarding a zoonotic disease hazard. This notification may be issued for a species, geographic area, type of work operation, and/or establishment." The Board has added the word "public" to clarify that this announcement must be of a public nature, and has added that the announcement must be for a "detected zoonotic ATP hazard." This change clarifies that alerts do not include fact sheets that are issued only for general informational purposes. Other than notifications for hantavirus, there are no current alerts for zoonotic ATPs in California, although there may be many "fact sheets" available for zoonotic diseases. The term "ATP" has been inserted into the definition of alert, and also into subsection (a)(2)(B)2 to clarify that this subsection only applies to alerts regarding zoonotic ATPs.

If an applicable alert has been issued, subsection (b) requires the employer only to develop effective procedures for reducing the risk of exposure to ATPs. This subsection does not mandate the use of "Tyvek" or any other specific type of personal protective equipment. Employers must determine what type of PPE is to be used, based on the hazards, work activities and other factors. Even in the presence of an applicable alert, respirators are not typically required for the disposal of an individual bird outdoors (pigeon or raptor) unless the employer has reason to believe that there will be a significant exposure to dusts potentially containing infectious pathogens.

<u>Comment #JV5:</u> The rulemaking file does not support the application of this section to "incidental wildlife exposures" or performance of low risk tasks.

<u>Response:</u> Some zoonotic ATPs may cause human disease with little contact. The standard only requires employers to identify and evaluate zoonotic ATP hazards, and to take corrective measures in accordance with Section 3203 and regulations pertaining to sanitation and personal protective equipment. Please see response to comment #JV2 for additional discussion.

Comment #JV6: Wording similar to the February 2007, Advisory Committee draft should be adopted. The commenter suggests inserting the term "occupational exposure" into the first line of subsection (a)(1)(A), and omitting subsection (a)(1)(A)8. The commenter also suggests modifying subsection (a)(2)(A) to state, "These procedures shall include applicable controls for the level of exposure and training," and adding a reference to a non-mandatory appendix containing control measures. If subsection (a)(1)(A)8 is retained, the commenter suggests changing the language to read "(8) Disease eradication and control operations involving the cleanup, decontamination or disinfection of areas contaminated with zoonotic aerosol transmissible pathogens."

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Response: The term "occupational exposure" is used in subsections (c) and (d) to identify those work areas and procedures to which the enhanced protections required for these higher risk environments is required. Subsection (a)(2)(A) has been reworded to clarify that employers are only required to address exposures to animals or their wastes under the IIPP, and to provide for sanitation and, where applicable, biosecurity and PPE. Subsection (a)(1)(A)8 has been changed to refer to "zoonotic ATP incident response." The term "zoonotic ATP incident response" is defined in subsection (a)(4) to mean "Operations conducted to control an outbreak of an animal disease involving the destruction and/or disposal of animals infected with zoonotic ATPs as defined above, and the clean up, decontamination and disinfection of areas and equipment associated with the infected animals or their remains."

Because of the variety of exposures addressed under this section, the Board does not see a utility in developing a non-mandatory appendix. Division staff have stated that they intend to work with industry sectors to develop materials to assist employers in complying with this regulation.

Comment #JV7: The term "applicable" should be inserted into subsection (a)(2)(B)2. The wording of this section should also be changed to include alerts issued regarding the potential of "occupational exposure to aerosol transmissible zoonotic infection." Similarly, Subsection (b)(1) should be changed to refer to an "applicable alert regarding the potential for occupational exposure to aerosol transmissible zoonotic infection." Subsection (b)(3) should be modified to state that respirator use is only required when there are "excessive amounts of animal related dusts."

<u>Response</u>: Subsection (a)(2)(B)2 has been modified. The term "zoonotic ATP infection" has replaced the term "zoonotic infection," in order to clarify that the alert must be in regards to an aerosol transmissible pathogen. This sentence has been further modified to indicate that the alert must be "applicable to the employer's operations based on the conditions specified in the alert, e.g. the geographic area, and species or type of animal." Further, the definition of "alert" has been modified to include a public announcement or notification of "a detected zoonotic ATP hazard."

In regards to the specific suggestion that the additional control measures in subsection (b) be triggered by an alert from the CDC, CDFA, CDFG, USDA, or USDOI for "occupational exposure to aerosol transmissible zoonotic infection," it is not within the mission or expertise of these agencies to address occupational exposure, which is assigned in California to Cal/OSHA. The public alerts issued by these agencies do not specifically address occupational exposures, and the Board cannot impose upon these agencies the duty to define them or to prescribe protective measures for employers to follow.

In regards to subsection (b)(3), number 3 (now renumbered as (C)) the existing language contains the criteria by which respirator use is to be required, which is that the dusts in the environment are reasonably likely to be an aerosol infection hazard to employees. The suggestion of the commenter that respirator use be triggered by the amount of the dust does not take into account that the quantity of dust is not the only criteria for determining whether there is

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an aerosol infection hazard. Other criteria, such as the nature of the dust and pathogen involved, and whether other control measures are in place to reduce airborne dust are also important for determining whether respirators must be used.

<u>Comment #JV8:</u> The Board should return this proposal to the advisory committee for "full and complete discussion of the issues raised in the proposal that were not previously addressed by the committee."

<u>Response</u>: Extensive discussion of this proposal occurred at advisory meetings and in other venues in which stakeholders were present. The issues raised by this commenter and others have been addressed in these responses, and as appropriate, in modifications of the proposal. Zoonotic diseases are an increasingly recognized hazard for employees, and this proposal adopts a reasonable approach to reducing risks to employees.

Mark Catlin, Industrial Hygienist, Service Employees International Union, by oral comment at the August 21, 2008, Public Hearing

<u>Comment #MC1:</u> The commenter spoke in support of the proposed standard.

Response: The Board thanks the commenter for his support.

Ken Nishiyama Atha, Regional Administrator, Region IX, Occupational Safety and Health Administration, U.S. Department of Labor, by letter dated September 18, 2008

<u>Comment #KNA1:</u> As proposed, the standard is at least as effective as applicable counterpart federal standards in protecting employees from aerosol transmissible diseases – zoonotics.

<u>Response:</u> The Board thanks the commenter for his comments and participation in the rulemaking process.

Response to comments from Board Member Jonathan Frisch received at the August 21, 2008, Public Hearing

<u>Comment #JF1:</u> In response to comments by Dr. Materna on behalf of CDPH, Dr. Frisch asked her whether the argument of the construction and utility industries regarding incidental exposure and personal protective equipment had merit.

<u>www.apgea.army.mil/ENTO/TG142.HTM</u>, which addressed hazards to workers in construction and related operations resulting from bird and bat droppings, and relating several cases of serious or fatal disease (U.S. Army 1992). The CDC reported on an outbreak of histoplasmosis relating

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to excavation of soils and repair of an outdoor pipe (CDC 2004). The Massachusetts Department of Public Health reported on a tularemia outbreak in 2001 in Martha's Vineyard, and advised that "it appeared that persons recently involved in outdoor occupations, such as landscapers or construction workers, were at an increased risk of disease." It should be noted that many zoonotic diseases remain unreported and undetected because they have symptoms similar to other self-resolving diseases such as influenza or digestive upsets.

MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE 15-DAY NOTICE OF PROPOSED MODIFICATIONS

No further modifications to the information contained in the Initial Statement of Reasons are proposed as a result of the 15-day Notice of Proposed Modifications mailed on March 25, 2009.

Summary and Response to Written Comments:

Anne Katten, MPH, Pesticide and Work Safety Project, California Rural Legal Assistance Foundation (CRLA), by letter dated April 7, 2009

<u>Comment #AK1:</u> The definition of Zoonotic ATP incident response in the revised proposal deletes reference to areas potentially contaminated with aerosols of transmissible zoonotic disease pathogens. At a minimum, areas where a disease outbreak is strongly suspected should be captured by this definition in order to protect workers while confirmatory laboratory tests are in process.

Response: The new definition of "zoonotic ATP incident response" is used to define one type of work operation that is included within the scope of the standard. Most areas in which animals or their wastes or remains are likely to be present are included within other subsections of the scope, in subsections (a)(1)(A)1 through (a)(1)(A)7. The proposed standard is structured so that all employers whose employees work in facilities, services or operations in which they are exposed to animals and associated wastes (and who therefore may work in areas potentially contaminated with zoonotic ATPs) are required to address these exposures through their injury and illness prevention plan (IIPP). Employers are required to identify and evaluate hazards, to take measures to correct those hazards, to provide training to employees, investigate occupational injuries and illnesses, provide sanitation measures, and where applicable, personal protective equipment and establish any necessary biosecurity measures. The language change addressed by the commenter does not change this scope.

Additional protection is required when certain triggering circumstances are met, as addressed in the application section, subsection (a)(2). These triggers were not substantially changed in the notice of proposed modification (NPM).

Additional protection is triggered under subsection (c) when the California Department of Food and Agriculture (CDFA) or United States Department of Agriculture (USDA) issue infection control orders for a zoonotic ATP that apply to an establishment. Subsection (c) requires

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employers to limit access to areas in which employees are exposed to potentially infectious animals, and to take additional precautions in these areas. These orders may be issued not only on the basis of suspected or diagnosed infection, but also on the basis of increased risk of infection due to geographic proximity or other direct or indirect contact with a source of zoonotic ATPs. This provision is meant to protect employees in areas that house animals identified as being at increased risk of zoonotic ATP infection during a period when animals may be infectious, but not yet manifesting clinical signs of disease, and during periods when a disease is suspected but not confirmed.

The definition of "Zoonotic ATP incident response" is "Operations conducted to control an outbreak of an animal disease involving the destruction and/or disposal of animals infected with zoonotic ATPs and the clean up, decontamination and disinfection of areas and equipment associated with the infected animals or their remains." This definition should be read in conjunction with the definition of "animals infected with zoonotic ATPs" which includes animals that "(1) have been diagnosed with a zoonotic ATP through recognized testing methods or (2) meet the clinical definition of a suspect case of infection with a zoonotic ATP or (3) have been identified by the CDFA, CDFG, USDA or USDOI as requiring isolation, quarantine or destruction due to suspected or confirmed infection." This definition was not changed in the NPM, and it includes animals in which infection is "strongly suspected" as suggested by the commenter, "while confirmatory laboratory tests are in process." The protections in subsection (d) are triggered by these exposures.

Therefore the Board believes that no change is necessary to this proposal to ensure that employees are protected during a period in which confirmatory diagnostic tests are being performed.

Comment #AK2: The commenter objects to the deletion in the NPM of language previously included in subsection (a)(2)(A) that required training to include recognition of conditions in the workplace which require additional control measures. Such training is critical because of the dynamic nature of disease outbreaks.

Response: Subsection (a)(2)(A) was restructured in response to comments in order to clarify that in the absence of triggering circumstances identified in (a)(2)(B) through (a)(2)(G), employers are required only to address zoonotic ATP hazards through the IIPP and other existing requirements. Section 3203 requires employers to have a method of communication with employees about hazards in the workplace. In the case of zoonotic ATPs an effective IIPP would include a means by which employees can inform the employer of conditions such as an unusual illness or death among animals in the establishment, which would then trigger the employer's responsibility to investigate the hazard and take appropriate measures. Section 3203 also requires employers to train employees about hazards and corrective measures and to provide additional training when hazards are newly recognized. Therefore the Board believes that subsection (a)(2)(A), as reworded, requires employers to train employees about the recognition of the signs of a zoonotic ATP hazard among animals in the establishment, how they can communicate this hazard to the employer, and protective measures they will take.

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<u>Comment #AK3:</u> The commenter supports the revision of subsection (d)(4) to require that the employer demonstrate through objective evidence that risks have been eliminated, as a condition of waiving respiratory protection requirements.

Response: The Board thanks the commenter for her support.

Comment #AK4: The commenter had previously stated that the Board should require change rooms and shower facilities in all farm animal handling operations because disease outbreaks can occur suddenly and spread rapidly. The commenter disagrees with the Board's response to that comment in the NPM, which stated that in the absence of a detected ATP hazard, the necessity for requiring additional specific sanitation and control measures had not been demonstrated during the advisory process. Jacqueline Nowell, Director of Occupational Health and Safety for the United Food and Commercial Workers Union (UFCW) provided information during the advisory meeting that workers at poultry facilities do not change their clothing before going home. The CRLA also raised concerns at an advisory meeting about poultry and dairy workers wearing clothing heavily contaminated with dust laden with animal urine and feces home, or to second jobs at other farm animal handling facilities. Therefore it is obvious that during normal activities, and especially in preparation for laundering contaminated clothing, dust will be inhaled by workers and their families.

Response: The Board recognizes that while some farms and animal handling operations in California have extensive sanitation and biosecurity facilities, others may not. The response to the previous comment was not intended to minimize the general sanitation issues mentioned by the commenter and by participants in the advisory meetings. However, comments during the advisory process, and a review of literature by Division staff, did not establish that the lack of a requirement for showers and change rooms had resulted in the employees contracting infection with zoonotic ATPs, in the absence of the triggering circumstances identified in subsections (a)(2)(B) through (a)(2)(G). Employers who plan to continue operations in the event of a disease outbreak should plan for how they will provide enhanced sanitation and biosecurity measures for employees in those operations.

The Board understands that there may be pathogens present in many animal wastes. However, it is beyond the scope of the current proposal to address the general issues of sanitation in animal handling operations that may exist prior to the triggering circumstances identified in subsections (a)(2)(B) through (a)(2)(G).

<u>Comment #AK5:</u> The commenter urges the Board to consider these comments and to proceed rapidly to adopt this standard, in order to protect employees in California who work with farm animals, wildlife and exotic animals. CRLA is eager to assist in developing policy for implementation of this standard in farm animal handling operations.

Response: The Board thanks the commenter for her support, and offer of assistance.

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Rick Kreutzer, MD, Chief, Division of Environmental and Occupational Disease Control, California Department of Public Health (CDPH), by letter dated April 10, 2009

Comment #RK1: Barbara Materna, Chief of the Occupational Health Branch testified on behalf of CDPH in support of the original version of the proposed zoonotic ATD standard at the August 21, 2008, hearing. Following the hearing, Dr. Materna solicited technical comments on the proposed standard from a number of CDPH staff in communicable disease, occupational health and laboratory science, and provided those comments to Division staff. Those comments were thoughtfully considered, and on the whole were satisfactorily addressed in the modifications in the present version. The CDPH enthusiastically supports the adoption of Title 8, Section 5199.1, which would make California the first state in the nation to enact a regulation that protects workers from zoonotic aerosol transmissible diseases. The CDPH is available to assist Cal/OSHA in education and outreach efforts once this standard is adopted.

<u>Response:</u> The Board thanks the commenter for his support, and thanks the CDPH for their assistance in developing this proposal and their offer of assistance in education and outreach efforts.

John C. Vocke, Attorney, Pacific Gas and Electric Company, by facsimile dated April 10, 2009

<u>Comment #JV1:</u> PG&E appreciates the modifications to the proposal made by the Board and Division staff in response to their initial comments. The commenter believes that the modifications will permit the continued safe operation of PG&E's raptor protection program.

<u>Response:</u> The Board thanks the commenter for this assessment of the modifications of the proposal.

Comment #JV2: Subsection (a)(2)(A) should be changed to replace the term "preventing" as follows, "...maintain effective procedures for <u>assuring safe and healthful working conditions for</u> employee exposure to zoonotic aerosol transmissible pathogens in accordance with Section 3203 of these orders." This change is recommended to be consistent with Labor Code section 6300, and would establish a clear obligation for employers to provide a safe and healthful place of employment. The term "preventing" establishes a duty to develop preventive procedures that could not be met in many field situations.

Response: The language used in the NPM is intended to integrate employers' zoonotic ATD exposure prevention requirements with other injury and illness prevention requirements pursuant to Section 3203. Under Section 3203, employers are required to identify and evaluate hazards, and take corrective action in a timely manner in accordance with the severity of the hazard. The Board notes that the language suggested by the commenter does not provide as much clarity to employers regarding how zoonotic ATP hazards are to be addressed. The commenter appears to equate the concept of absolute prevention with the directive in the proposed provision for employers to utilize effective exposure prevention measures. However, use of the procedural approach coupled with the qualifier "effective" in the proposed provision would only constitute

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meaningless surplus wording if the intent were to imply that adequate compliance means that exposure will never occur. The employer is obligated to be "effective" (see Labor Code section 6401.7(a)) and reasonable (see Labor Code sections 6401 and 6403) in choosing and implementing procedural measures to address potential exposure to zoonotic ATDs. As discussed in the NPM, these preventive measures may include common measures such as gloves, the use of dust minimization techniques, and provision of required sanitation facilities. For these reasons, the Board declines to make additional modifications to this subsection.

Comment #JV3: Subsection (a)(2)(B)(2) imposes a duty on employers to monitor alerts from a multiplicity of state and federal agencies. PG&E is also concerned that the term "alert" is not clearly defined in terms of what is produced by different agencies, for example a USDA alert may differ from a CDFA alert. For this reason, the Division should be the "clearinghouse" for zoonotic alerts.

Response: Under California and federal law, public health, agricultural agencies and agencies regulating wildlife operations have been given the responsibility for issuing public health alerts regarding zoonotic ATP hazards. Introducing a requirement for the Division to act as a "clearinghouse" may introduce a delay in employers' responses to these alerts that may adversely impact the protection of employees. The Division also does not have the legal authority to override an alert issued by the USDA, CDFA, or other designated agency.

While it may be true that the designated agencies use different procedures for issuing alerts, there are procedures in place to assure that consistent information will be issued, including statewide public information plans for detection of diseases such as zoonotic avian influenza. Generally, disease notifications are announced widely, through print and broadcast media. Employers can also access alerts issued by the CDPH, Veterinary Public Health Section, through their web page and public information phone number. Similarly, local health departments maintain web pages and phone numbers for public information. The Board believes that these agencies will provide adequate notice to employers.

Similar comments were provided in response to the Notice of Proposed Rulemaking. The Board addressed these issues in the NPM by adding the word "public" to clarify that the announcements triggering the additional precautions must be of a public nature. The Board also added language stating that the announcement must be for a "detected zoonotic ATP hazard," to differentiate between alerts triggering the requirements of subsection (b) and general information provided to the public regarding zoonotic diseases. The Board believes that the modifications in the NPM sufficiently address this issue, and declines to make any further modification.

Comment #JV4: PG&E recommends that the term "surveillance" be restored to the proposed regulation to prevent confusion with other medical services that may be provided in response to a zoonotic ATP exposure. In the event of a zoonotic ATP exposure incident, services may be provided by a private physician or through the workers compensation system. In some cases the records of these services may not be available to the employer. The record retention requirement for medical records should be limited to the medical surveillance records required by the

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proposed regulation. Section (e)(3) should be changed to read "Records of medical surveillance, required by this section, shall be maintained."

Response: The Board notes that the term "medical services" was introduced to prevent confusion with the common language use of the term "surveillance," that does not typically include medical services such as vaccination and prophylaxis. Subsection (d)(8) clearly specifies the medical services that must be provided to employees who are exposed to animals that are infected with zoonotic ATPs, such as during a zoonotic ATP incident response. Subsection (d)(8)(F) specifically identifies the information a physician or other licensed health care professional (PLHCP) will provide to the employer.

Subsection (e)(3) refers requirements to maintain employee medical records as confidential in accordance with Section 3204, which is equivalent to the federal regulation 29 CFR 1910.1020. These are existing requirements. The employer's only such records may be the written reports from the PLHCP, as identified in this section. However, all employee medical records, whether related to zoonotic ATP exposures or not, must be maintained in accordance with Section 3204 in order to maintain federal equivalence. The Board therefore declines to make further changes in this subsection.

Ken Nishiyama Atha, Regional Administrator, Region IX, Occupational Safety and Health Administration, U.S. Department of Labor, by letter dated March 27, 2009

<u>Comment #KNA1:</u> As proposed, the 15-day modification to the ATD-Zoonotic standard continues to provide protection at least as effective as applicable counterpart federal standards in protecting employees from aerosol transmissible diseases – zoonotics.

<u>Response:</u> The Board thanks the commenter for his comments and participation in the rulemaking process.

ADDITIONAL DOCUMENTS RELIED UPON

- Balazy A, Toivola M, Adhikari A, Sivasubramani K, Reponen T, and Grinshpun S. 2006. Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks? Am J Infect Control 34:51-57.
- Bosman A, Mulder YM, de Leeuw JRI, et al. "Executive Summary Avian Flu Epidemic 2003: Public Health Consequences," RIVM report 630940004/2004, available from: http://www.rivm.nl/bibliotheek/rapporten/630940004.html
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These documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the Standards Board Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, California.

ADDITIONAL DOCUMENT INCORPORATED BY REFERENCE

Biosafety in Microbiological and Biomedical Laboratories (BMBL). Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition, CDC and National Institutes for Health, 2007.

This document is too cumbersome or impractical to publish in Title 8. Therefore, it is proposed to incorporate the document by reference. Copies of this document are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the address listed above.

DETERMINATION OF MANDATE

These standards do not impose a mandate on local agencies or school districts as indicated in the Initial Statement of Reasons.

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ALTERNATIVES CONSIDERED

The Board invited interested persons to present statements or arguments with respect to alternatives to the proposed standard. No alternative considered by the Board would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the adopted action.